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|-----------------|-------------|---------------------------|---------------------|------------------|
| 09/489,079      | 01/21/2000  | Patricia A. Billing-Medel | 6451.US.P1          | 5338             |

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STEVEN F. WEINSTOCK  
ABBOTT LABORATORIES  
100 ABBOTT PARK ROAD  
DEPT. 377/AP6A  
ABBOTT PARK, IL 60064-6008

EXAMINER

EPPS, JANET L

ART UNIT

PAPER NUMBER

1635

29

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/489,079

Applicant(s)

BILLING-MEDEL ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 52-81 is/are pending in the application.
- 4a) Of the above claim(s) 62-69 and 71-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 52-61, 70 and 77-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 52-61, 70, and 77-81, drawn to the elected invention in Paper # 7, are currently under examination.

***Continued Examination Under 37 CFR 1.114***

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-11-02 has been entered.

***Response to Amendment***

4. The Declaration filed under 37 CFR 1.132 filed 2-3-03 is insufficient to overcome the rejection of claims 52-61, 70, and 77-81 based upon 35 USC § 101 and 112, 1<sup>st</sup> paragraph as set forth in the last Office action because: the facts presented in the Granados Declaration are not germane to the rejection at issue and it fails to provide any evidence that the BS322 polypeptides according to SEQ ID NO: 25-28 are equivalent to the NY-BR-1 breast cancer antigen polypeptide.

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*Response to Arguments*

5. Claims 52-61, 70, and 77-81 remain rejected under 35 USC § 101 and 112, first paragraph, for the reasons of record set forth in the Official Action mailed 5-16-02.

Applicant's arguments filed 2-3-03 have been fully considered but they are not fully persuasive. Applicants traverse the instant rejection on the grounds that in view of the Declaration of Dr. Granados, the instant rejection should be withdrawn. Moreover, Applicants submit that this declaration answers many of the questions raised by the Examiner in the prior Office Action.

However, contrary to Applicant's assertions, the sequence alignments of Dr. Granados further supports the instant rejection. The Granados Declaration provides evidence that there is significant overlap between the consensus nucleotide sequence of BS322 (SEQ ID NO: 9) and NY-BR-1, and between the polypeptide sequences of SEQ ID NO: 24-25 and the protein sequence of NY-BR-1. However, Granados clearly states that BS322 lacks 185 nucleotides that are present in NY-BR-1, and points out the differences between the amino acid sequences of SEQ ID NO: 24-25 and the NY-BR-1 sequence. Although there is significant homology between the nucleotide and amino acid sequences of BS322 and NY-BR-1, they clearly not the same molecule, as evidenced by Granados Declaration which shows the homology between BS322 and NY-BR-1. Moreover, the Granados Declaration does not address the polypeptides according to SEQ ID NO: 26-28. Granados also clearly states that the BS322 nucleotide sequence comprises only 2683 nucleotides in length and the NY-BR-1 sequence is 4463 nucleotides in length, there are almost 2000 nucleotides unaccounted for between BS322 and NY-BR-1. As stated in the prior Office Action, the polypeptides according to the present

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invention range in length from 38-317 amino acids, however the one open reading frame of NY-BR-1 produces a protein of 1341 amino acids.

Applicants have not provided sufficient evidence that the isolated polypeptides according to SEQ ID NO: 24-28 are equivalent to the NY-BR-1 breast cancer antigen polypeptide.

*Conclusion*

6. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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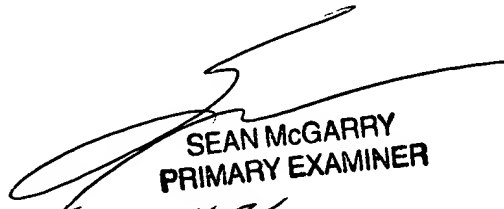
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford, Ph.D.  
Examiner  
Art Unit 1635

*JLE*  
April 5, 2003

  
SEAN MCGARRY  
PRIMARY EXAMINER  
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